DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
FAX: 949-798-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 31, 2004

W/L 46-04

Geoffrey Vanden Heuvel
Owner
J & D Star Dairy
7551 Kimball Ave.
Chino, CA 91710

Dear Mr. Vanden Heuvel:

Our records reflect you are the owner of J & D Star Dairy located at 7551 Kimball Avenue, Chino, CA. An investigation of your dairy operation conducted by a Food and Drug Administration (FDA) investigator on July 6-8, 2004, confirmed that you offered animals for sale for slaughter as food which is in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (henceforth the "Act"). You also caused the adulteration of an animal drug within the meaning of Section 501(a)(5) of the Act because the drug was used in a manner that does not conform with its approved use or the extra-label use regulations at 21 C.F.R. Part 530.

On or about February 20, 2004, you sold a culled dairy cow identified by USDA Laboratory report 427944 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.07 parts per million (ppm). Additionally, on or about February 25, 2004, you sold a culled dairy cow identified by USDA Laboratory report 427951 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.16 ppm. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle [21 CFR 556.510]. The presence of penicillin above established tolerance levels in the edible tissues from these animals caused the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under improper conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for the appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

It was further determined that you are using drugs in a manner contrary to their approved labeling. Such extra-label use is not permitted, except by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and otherwise in compliance with the limitations set forth for specific extra-label uses [21 CFR Part 530]. Your use of drugs in any manner other than as labeled causes those drugs to be unsafe under Section 512(a)(1)(B) of the Act, and adulterated within the meaning of Section 501(a)(5) of the Act.

- You are adulterating injectable penicillin G procaine that you use on dairy cattle in a manner contrary to the approved labeling. The labeled dose is for 1 cc per 100 pounds of body weight. Your use of 30ccs for cows weighing approximately 1300 pounds is in excess of the labeled directions.

Unless explicitly directed by a licensed veterinarian under a valid veterinarian-client-patient relationship, it is a violation of the law for any person to use any drug in any manner other than as labeled. This is true regardless of whether or not such use results in an illegal drug residue. The FDA is concerned not only about the indiscriminant use of drugs, but also the long term ramifications of such use, especially when such use is not in agreement with the approved labeled directions. The FDA expects licensed veterinarians to be aware of these concerns and consider them when determining appropriate drug usage, including the condition being treated as well as the milk and meat withdrawal times.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse which ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action, such as injunction, without further notice. This letter constitutes official notification under the law and provides you an opportunity to correct the violations.

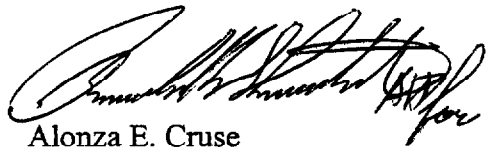
Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should

include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made. If you have any questions or need clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer, at telephone number (949) 608-4439.

Your written response should be directed to:

Pamela B. Schweikert
Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Sincerely,



Alonza E. Cruse
District Director